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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,606	03/28/2006	Jo Klaveness	PN0368	6864

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EXAMINER	
PERREIRA, MELISSA JEAN	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,606	KLAVENESS ET AL.	
	Examiner	Art Unit	
	Melissa Perreira	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 March 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/28/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

Pages 2-4 of prior art reference WO02/26776 are missing from the application.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 13,14,16-18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuthbertson (WO02/26776).

3. Cuthbertson (WO02/26776) discloses a peptide based contrast agent of the formula V-L-R where V is a vector moiety, L is a linker moiety and R is a reporter moiety (ex. Detectable in an imaging procedure, such as in vivo imaging) (p5, paragraph 4; p6, paragraph 1). The peptide vector moiety has an affinity for the integrin vus3 receptor (p5, paragraph 2; p13, paragraph 5). The contrast agents of the disclosure may be formulated into a pharmaceutical composition (p11, paragraph 4) for in vivo imaging of receptors associated with angiogenesis and diseases associated with angiogenesis, such as colorectal cancer (p1, paragraph 1). At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the peptide based contrast agent Cuthbertson for imaging colorectal cancer as it is disclosed in the art.

It is respectfully pointed out that instant claim 23 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

4. Claims 13-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Maten et al. (*Gastroenterol.* **2002**, *122*, 406-414).

5. Maten et al. (*Gastroenterol.* **2002**, *122*, 406-414) discloses cathepsin B sensing NIR fluorochrome probes comprising Cy5.5 (cyanine dye) containing cleavage sites, and a partially pegylated poly-L-lysine for imaging of the colon (p408, paragraph 3; figure 2). Colonic adenomas can be visualized after injection of the NIRF probe into a mouse (figure 5) and colonic adenomatous polyps ultimately lead to carcinoma formation and their detection has been shown to reduce the incidence of colorectal cancer. The probes are nonfluorescent in their native state but upon enzymatic cleavage the agent becomes fluorescent in the near-IR (figure 1; p412, paragraph 2). At the time of the invention it would have been obvious to one ordinarily skilled in the are to utilize the cathepsin B sensing NIR fluorochrome probes of Maten et al. for imaging the colon as they can easily be integrated into existing endoscopic systems, to

provide high resolution, real time imaging and may also have a significant impact on diagnosis of a very early stage of intestinal disease (p414, paragraph 4).

It is respectfully pointed out that instant claim 23 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

6. Claims 13-15,17,18 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weissleder et al. (*Nature Biotech.* **1999**, *17*, 375-378).

7. Weissleder et al. (*Nature Biotech.* **1999**, *17*, 375-378) discloses NIRF probes for in vivo imaging comprising poly-L-lysine, MPEG and Cy5.5 (cyanine dye) (abstract; p375, paragraph 4). The NIRF probes of the disclosure are enzymatically activatable, thus producing fluorescence upon enzymatic cleavage (p375, paragraphs 2, 4 and 5). The NIRF probes were internalized into colon adenocarcinoma via uptake through fluid phase endocytosis thus indicating the feasibility of using these for the detection of primary tumors in the colon, such as colon cancer (p376, paragraph 1; p377, paragraph 1). At the time of the invention it would have been obvious to one ordinarily skilled in the art to utilize the NIRF probes of Weissleder et al. for imaging colon caner in a

patient as it is known in the art and are advantageous as they detect early stage tumors in vivo (abstract).

It is respectfully pointed out that instant claim 23 is a product-by-process limitations. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed Cir. 1985). See MPEP 2113.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

9. A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

10. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 13-18 and 20-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 13-20 of copending Application No. 10/573,604. Although the conflicting claims are not identical, they are not patentably distinct from each other because the contrast agent of the instant claims anticipates the contrast agent of 10/573,604 whereas both contain V-L-R (V is a vector moiety, L is a linker and R is a reporter) and have molecular weights below 10000 Daltons. The R moieties of both disclosures are cyanine dyes that fluoresce upon enzymatic cleavage, V moieties are peptides and the contrast agents target receptors in a subject. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The contrast agents for the disclosures are the same and should therefore be capable of the same functions.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 13-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3-9 and 12 of copending Application No. 10/582,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the contrast agent of the instant claims anticipates the contrast agent of 10/582,679 whereas both contain V-L-R (V is a vector moiety, L is a linker and R is a reporter). The R moieties of both disclosures are dyes that fluoresce upon enzymatic cleavage, V moieties are peptides

and the contrast agents target E-cadherin in a subject. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The contrast agents for the disclosures are the same and should therefore be capable of the same functions and properties, such as having a molecular weight below 10000 Daltons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 13-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3-9 and 12 of copending Application No. 10/582,680. Although the conflicting claims are not identical, they are not patentably distinct from each other because the contrast agent of the instant claims anticipates the contrast agent of 10/582,680 whereas both contain V-L-R (V is a vector moiety, L is a linker and R is a reporter). The R moieties of both disclosures are dyes that fluoresce upon enzymatic cleavage, V moieties are peptides and the contrast agents target cathepsin B in a subject. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The contrast agents for the disclosures are the same and should therefore be capable of the same functions and properties, such as having a molecular weight below 10000 Daltons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Claims 13-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3-9 and 12 of copending Application No. 10/582,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because the contrast agent of the instant claims anticipates the contrast agent of 10/582,842 whereas both contain V-L-R (V is a vector moiety, L is a linker and R is a reporter). The R moieties of both disclosures are dyes that fluoresce upon enzymatic cleavage, V moieties are peptides and the contrast agents target COX-2 in a subject. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The contrast agents for the disclosures are the same and should therefore be capable of the same functions and properties, such as having a molecular weight below 10000 Daltons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 13-23 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3-8 and 12 of copending Application No. 10/582,893. Although the conflicting claims are not identical, they are not patentably distinct from each other because the contrast agent of the instant claims anticipates the contrast agent of 10/582,893whereas both contain V-L-R (V is a vector moiety, L is a linker and R is a reporter). The R moieties of both

disclosures are dyes that fluoresce upon enzymatic cleavage, V moieties are peptides and the contrast agents target COX-2 in a subject. "The recitation of a new intended use for an old product does not make a claim to that old product patentable." *In re Schreiber*, 44 USPQ2d 1429 (Fed. Cir. 1997). The contrast agents for the disclosures are the same and should therefore be capable of the same functions and properties, such as having a molecular weight below 10000 Daltons.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa Perreira whose telephone number is 571-272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MP
May 30, 2007

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER